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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/996,343      | 11/28/2001  | Gunnar J. Hanson     | 2676/07             | 3226             |

26648 7590 06/30/2003  
PHARMACIA CORPORATION  
GLOBAL PATENT DEPARTMENT  
POST OFFICE BOX 1027  
ST. LOUIS, MO 63006

EXAMINER

SHIPPEN, MICHAEL L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1621

DATE MAILED: 06/30/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/996,343

Applicant(s)

HANSON ET AL.

Examiner

MICHAEL L. SHIPPEN

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 37-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **Part III DETAILED ACTION**

#### ***Specification***

The amendment filed November 28, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure for reasons of record. Page 17 of the specification is noted but not seen to support the language in question. The specification indicates that a hypertensive subject as a person afflicted with or susceptible to the effects of hypertension if not treated to prevent or control the condition. This is merely a definition of a hypertensive subject. This is not a statement that the instant compounds actually possess preventive properties. In fact the only data presented represents that the instant compounds may possess 70% inhibition of renin (page 66 of the specification) which does not appear to prevent hypertension but rather helps control the condition.

Applicant is required to cancel the new matter in the reply to this Office Action.

#### ***Double Patenting***

The rejections for type-type double patenting were overcome by the terminal disclaimer filed with applicants' amendment. It is noted that the Patent Number of USP 6,342,624 had the last two numbers transposed in the rejection of record. However, the correct patent number was used by applicants in the terminal disclaimer.

#### ***Claim Rejections - 35 USC § 112***

Claims 37-47 are rejected under 35 U.S.C. § 112, first paragraph. The claimed embodiment of "prevention" lacks description and enablement in the specification as

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filed for reasons of record. Page 17 of the specification is noted but not seen to support the language in question. The specification indicates that a hypertensive subject as a person afflicted with or susceptible to the effects of hypertension if not treated to prevent or control the condition. This is merely a definition of a hypertensive subject. This is not a statement that the instant compounds actually possess preventive properties. In fact the only data presented represents that the instant compounds may possess 70% inhibition of renin (page 66 of the specification) which does not appear to prevent hypertension but rather helps control the condition.


### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael L. Shippen** whose telephone number is **(703) 308-4635**. The Examiner's normal tour of duty is 7:30 AM to 4:00 PM. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is **(703) 308-1235**. The official group FAX machine number is **(703) 308-4556**.

MShippen  
June 27, 2003

  
**MICHAEL L. SHIPPEN**  
**PRIMARY EXAMINER**  
**ART UNIT 1621**